

REMARKS

Claims 1-24 are pending in the application.

Claims 1-10, 13, 14, and 17-23 stand rejected under 35 U.S.C. § 102(e).

Claims 1-24 stand rejected under 35 U.S.C. § 103(a).

Claims 13, and 20 have been amended to address the objection relating to a duplicate claim as well as to correct the spelling of “atherosclerosis”.

The present invention as currently claimed provides a new pharmaceutical composition comprising: (a) an effective amount of HMG-CoA reductase inhibitor; and (b) an effective amount of a compound that inhibits cholesterol synthesis at a point between the formation of acetate and mevalonate.

THE REJECTION UNDER 35 U.S.C. § 102 (e)

Claims 1-10, 13, 14, and 17-23 stand rejected under 35 U.S.C. § 102 (e) as being anticipated by Cooper et al. US 2003/0232796 A1 who teach a pharmaceutical composition comprising policosanol and HMG-Co reductase inhibitors.

One of the Applicant's (Isaac Angres – inventor of claims 1-10, 13, 14, and 17-23) is filing herewith an affidavit under 37 CFR 1.131 (see MPEP 715.04 (B)) which is believed to render moot the rejection of Claims 1-10, 13, 14, and 17-23 under 35 U.S.C. § 102(e) as being anticipated by Cooper et al. US 2003/0232796 A1.

It should be noted however, that the Cooper et al. invention is focused on a policosanol composition having a particle size less than 2000 nm and also includes at least one surface stabilizer. The composition may also include an HMG-Co reductase

inhibitor. In contradistinction, Applicants' invention is devoid of any particle size limitation or a surface stabilizer.

THE REJECTION UNDER 35 U.S.C. § 103 (a)

The rejection of claims 1-24 under 35 USC § 103 (a) as being unpatentable over Cooper et al. in view of Brox U.S. Patent No. 4,744,988 is respectfully traversed.

The invention as presented in the currently pending claims is directed to compositions and methods for treating atherosclerosis, or for the reduction of plasma cholesterol using policosanol and HMG-CoA reductase inhibitors. The compositions are also claimed as softgel capsules containing policosanol and an HMG-CoA reductase inhibitor.

It is submitted that for the reasons set forth below in conjunction with distinguishing over each of the cited Cooper et al and Brox patents, that the currently pending claims are patentable over the cited art.

Cooper et al. (2003/0232796 A1) is directed to nanoparticulate compositions of policosanol having an average particle size of less than 2000 nanometers and it requires the presence of a surface stabilizer. Cooper et al. also suggest that additional actives such as statins may be combined with the surface stabilized policosanol. It is respectfully submitted that applicants' invention is not concerned with surface stabilized policosanol of a particle size of 2000 nanometer or less. Applicants' composition is simply a combination of policosanol and an HMG-CoA reductase inhibitor without surface stabilizers or particle size limitations. In any event, it is respectfully submitted that

Cooper et al. is no longer a reference in view of the affidavit under 37 CFR 1.131.

Applicant submits further that Brox does not cure the deficiencies of the Cooper et al. teachings. Applicants' soft gel capsules require that they contain policosanol and an HMG-CoA reductase inhibitor. Brox capsules lack the active ingredients of the instant invention.

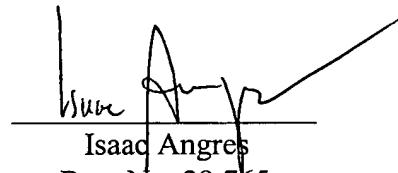
Accordingly, in view of the above arguments which are believed to be based on a fair reading of the Brox disclosure, it is respectfully submitted that Brox does not teach or suggest the present invention as currently claimed; namely, a composition containing policosanol and an HMG-CoA reductase inhibitor which has been encapsulated in a soft gel capsule. Furthermore, the deficiencies of the Brox disclosure do not close the gap between Cooper et al. (no longer a reference in view of the 37 CFR 1.131 affidavit) and the present invention. On these bases alone, the rejection should be withdrawn.

It is courteously submitted that the Office has failed to establish the criteria necessary to establish a *prima facie* case of obviousness as set forth in MPEP § 2142: the cited reference must teach or suggest all the claim limitations; there must be some motivation or suggestion, either in the reference or in the knowledge available to the skilled artisan, to modify the reference to arrive at the claimed invention, and there must be a reasonable expectation of success.

CONCLUSION

In view of the affidavit under 37 CFR 1.131 and the above remarks, it is respectfully submitted that the claims of the current Application are in condition for allowance. Reconsideration and withdrawal of the rejections are requested. The Examiner is invited to contact the undersigned at 703-418-2777 if he feels that further discussion may facilitate the resolution of any outstanding issues. An early indication of a Notice of Allowance is earnestly solicited.

Respectfully submitted,



Isaac Angres
Reg. No. 29,765

Date: November 26, 2004
2001 Jefferson Davis Highway - Suite 301
Arlington, VA 22202
(703) 418-2777
Procaps 003A